Ban on globally discarded drugs

*3. SHRI R.K. ANAND:
SHRI SANTOSH BAGRODIA:†

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that drugs/medicines that have been discarded globally are available freely in India such as Novalgin, Ciza Syspride, Droperol, Furozone, Lomefen, Nise, Nimulid, Furacin, Agarol, D'cold, Vicks Action 500, Sioril, Piperazine and Enteroquinol, etc.;

(b) if so, what are the reasons for banning sale of these drugs in other countries and their availability in the country; and

(c) the steps taken by Government to ban sale of these drugs in the country as also educate people about the ill effects of these drugs?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMDOSS): (a) to (c) A Statement is laid on the Table of the House.

Statement

(a) to (c) No, Sir. There is no system of global banning or discarding of drugs. Certain drugs or formulations banned or withdrawn in one or a few countries may continue to be marketed in other countries. The decision to ban or withdraw a drug by the regulatory authorities is normally based on the risk assessment process, which is influenced by a number of factors such as disease pattern in a country, indications and dosages of the drug permitted, varying reactions of certain ethnic groups in a given population, availability of safer substitutes and overall safety profile of the drug. It is well-known fact that administration of any drug is not absolutely free from side effects or adverse reactions in a statistically insignificant minority of the population.

There is an adequate mechanism in India to review the status of drug formulations as and when any serious adverse event is reported in the international journals, WHO newsletters or when a drug formulation is reported to have been withdrawn in some countries. The use of the drug, so reported, is assessed in consultation with the experts, based on

†The question was actually asked on the floor of the House by Shri Santosh Bagrodia.

available technical information, benefit-risk ratio, local needs etc. The matter is further considered by the Drugs Technical Advisory Board (DTAB), a statutory body under the Drugs and Cosmetics Act, 1940. Seventy six categories of drug formualtions, which were considered irrational or harmful in the context of present knowledge have so far been prohibited in the country by the Central Government. The DTAB has, from time to time, examined the safety profile and international status of drugs based on which their continued marketing has been permitted.

The rationality of the drugs mentioned in the question has earlier been examined by various Expert Committees, set-up for the purpose, from time to time. Based on the current knowledge available about the drugs and the nature of use in the country, these drugs were permitted to be used in the country and wherever considered necessary, restrictions were imposed on their use for certain indications only. These drugs also continue to be used in many other countries.

The drug Sioril, a branded product containing Oxyphenbutazone was withdrawn by the concerned manufacturer about 10 years back and is no longer available in the market.

The term 'globally discarded drugs' is a phrase lossely used by the media, publishing list of some drugs from time to time alleging their ban world over. Publication of such news-reports, which are not based on facts, creates a wrong impression that harmful or toxic drugs, not used in any country, are permitted to be used in India.

In view of such distorted coverage by the media, a high-level committee was constituted by Government of India in 2001 under the chairmanship of Director General of Health Services including a Member of Parliament to go into the problem of alleged internationally banned drugs being sold in the country and to suggest measures to resolve it. The Committee in its report submitted in May, 2002, noted that the mechanism in the country to examine and prohibit sale of drugs, which may be prohibited in some countries was satisfactory. The committee also expressed a view that the apprehension that internationally banned drugs continue to be marketed in the country, is not based on facts. It further observed that certain drugs like Analgin, Hydroxyquinoline, Phenylbutazone/Oxyphenylbutazone, Piperazine, Lynestrenol, withdrawn in some countries, continue to be marketed in many other countries including India. The decision to continue marketing of single ingredient

formulations of these drugs in India was taken in consultation with the medical experts subject to a cautionary statement and contra-indications being given on the label/package insert wherever required.

A National Pharmacovigilance Programme has recently been launched in the country to generate specific data on possible serious adverse reactions and their casual analysis. More than 30 centres at various Medical Colleges in the country have been involved in the programme.

SHRI SANTOSH BAGRODIA: Sir, I would like to know from the Hon. Minister what were the recommendations of the Emergency Pharmaceutical Issues Reviewing Committee on the issue of PPA, which was referred to the Committee in February, 2005. Even in the countries, like USA, Analgin had been banned way back in 1977. Even in Nepal it is not used. So, I would like to know from the hon. Minister what were the recommendations of the Committee and what steps have been taken in this regard.

DR. ANBUMANI RAMDOSS:. Sir, so far as the issue of banning drugs is concerned, I have answered on this particular issue many a times in this House. (*Interruptions*) There is nothing like 'global banning' of drugs. No drug can be banned globally.

SHRI SANTOSH BAGRODIA: Sir, I have not put any question on 'global banning'. I was asking ...(*Interruptions*)

DR. ANBUMANI RAMDOSS: I am coming to that. You are talking about Analgin. I am coming to the issue. Some drugs are sold in America but are banned in Europe; while some are sold in Europe, but are banned in America. And, it is not mandatory that if it is banned in America it should be banned in the rest of the world. Because of the local ethnic factors some drugs could be incorporated more in the Indian community. There are a log of other technical issues also.

Coming to the issue of Analgin, which have been said to be banned in America, we have a Drug Technical Advisory Board (DTAB). It consists of the experts from all over the country. If we have any issues either through any journal or through the WHO or through anybody else, they are referred to the DTAB to alert. They go around the country; they go around the world and gather information about it. They take a decision depending upon the local needs, the local factors and local scientific

issues, whether they could ban the concerned drug or not. Similar is the case with Analgin. In fact, Analgin is used in Australia, Finland, Germany, Hong Kong, Hungary, and in many other countries. The drug was never introduced in the USA and the UK. In fact, the WHO had issued a notice about agranulocytosis and other issues. We have gone to the DTAB with all these issues. It could be used in the country. The WHO says it Paracetamol could be used, Analgin could also be used. If Paracetamol has side-effects, same is the case with Analgin. The entire world is using the Paracetamol. The Government is very, very keen in this regard. There has been awareness at the highest level that no drug which is detrimental to Indian Society should be used. We have banned about 76 or 77 formulations of single drug entity, for which we had gone through the entire process. We have our own system. And, after going through the entire process we have banned these drugs because they were detrimental to the Indian society.

I am not aware about the recommendations of the Committee. I will bring the same to the kind notice of the hon. Member.

SHRI SANTOSH BAGRODIA: Sir, my second supplementary in this. A number of commercial advertisements of PPA-containing medicines, like, the D-Cold and Vicks Action 500, etc are still shown in the media. In fact, for any of these medicines, which should not be consumed, either the drug manufacturer or the Government has to educate the people and the doctors. What efforts, or, what laws the Government is planning in this regard so that the information goes to the public in the villages, in the towns, and also to the doctors so that they are not used?

DR. ANBUMANI RAMDOSS: Sir, through you, I would like to inform the august House that we have issued notifications in respect of the drugs that are banned to the Drug Controllers of the State, to the professionals, to the doctors, who are going to prescribe these drugs. In fact, the manufacturers also know that they will be penalised very heavily, even they can be jailed if they manufacture the banned drugs. And, of course, the pharmacists, who sell the banned drugs, can also be jailed. We are creating this type of awareness through the newspapers. In fact, the point is well taken and, in future, we are going to create a lot more awareness about the banned drugs which have been delisted from the Indian pharmacopoeia.

SHRIMATI BRINDA KARAT: Sir, I am afraid, I heard the Minister's reply now. I have read his written reply. I think, this is for the first time that we are hearing about a 'racial theory of drugs'. I don't know, he may have got some scientific evidence to say that if the health of a child, under twelve in the United States of America or in the whole of the European Union, is going to be adversely affected by having Nimulid, a child in India is not going to be affected. Sir, why I am raising the issue of this specific drug Nimesulide is because it is mentioned in the question, but in the reply of the Minister it is not mentioned. It is a very serious matter because there was a petition, filed in the High Court, in which it was said that Nimulid for the children under the age of twelve was contraindicated.

The Drug Controller Office of India has given false information to the courts saying that there is a ban in Switzerland. There is no ban in Switzerland and Belgium. In fact, Sir, there is a ban in Switzerland and Belgium. The multi-national company is a US Company which has manufactured this drug. In the whole of the United States and not even a single country in the European Union where children under 12 can have this drug. On the basis of false information given by the Drug Controller's Office, which I believe, is perjury, the court was misled, and, there is no ban in this country. I would like to know from the hon. Minister whether in the light of the fact that recently even in Italy this drug has been banned, will the Government of India consider banning this American drug, that is, Nimesulide, for children under 12? Part (b) of my question is: will they take action against those who have misled the court?

DR. ANBUMANI RAMDOSS: Sir, coming to the ethnic issue like some drugs can be taken up well by Indians or some can be taken up by the Americans, these are proven facts and experts....(*Interruptions*)....

SHRIMATI BRINDA KARAT: How are they proven facts? Where have they have proven? Sir, what is this? ...(*Interruptions*)... This is a new theory of recialism. Sir, this country has become a dumping ground for multinational companies....(*Interruptions*)...

MR. CHAIRMAN: Let him finish...(*Interruptions*)... Let him finish .....(*Interruptions*)...

SHRIMATI BRINDA KARAT: Sir, India has become a dumping ground for multinational companies....(*Interruptions*)...

MR. CHAIRMAN: Please let him finish.

SHRI DIPANKAR MUKHERJEE: Is this a case of .....(*Interruptions*)...

SHRIMATI BRINDA KARAT: Sir, India has become a dumping ground for drugs...(*Interruptions*)...

MR. CHAIRMAN: Please don't disturb.....(*Interruptions*)... Please don't interrupt...(*Interruptions*)...

श्री एस॰एस॰ अहलुवालिया: जो जानवरों के लिए हानिकारक है वह सब विश्व ...(**व्यवधान**) ये मनुष्यों की दवाइयों के लिए कह रहे हैं कि अमेरिका में दूसरी और हिन्दुस्तान में दूसरी है। ...(**व्यवधान**)

DR. ANBUMANI RAMDOSS: Let me answer the question ....(*Interruptions*)...

MR. CHAIRMAN: Let him answer the question.

DR. ANBUMANI RAMDOSS: Sir, our experts say that some of the drugs metabolised by Indians are not metabolised by the write skin people...(*Interruptions*)...

SHRIMATI BRINDA KARAT: Sir, he is totally misleading this House...(*Interruptions*)... Sir, this is a ...(*Interruptions*)... Sir, India is not a dumping ground for multi-national companies. ...(*Interruptions*)... Sir, this is not a dumping ground for multi-national companies. यह क्या तरीका है। Sir, in Portugal, there have been deaths of many children because of this drug.

श्री एस॰ एस॰ अहलुवालिया: हिन्दुस्तान के डाक्टर्स अमेरिका में नौकरियां करते हैं। ...(**व्यवधान**)

DR. ANBUMANI RAMDOSS: Sir, I am equally concerned like them.

SHRIMATI BRINDA KARAT: Then, why don't you ban the drug? Ban this drug for the children under 12.

DR. ANBUMANI RAMDOSS: It is not that if anybody wants to ban it ....(*Interruptions*)... It is not a question of banning or not banning it.

श्री सभापति: मैं इतना ही कह सकता हूं ...(**व्यवधान**)... मेरी सुनिए एक मिनट। ...(**व्यवधान**)

श्रीमती वृंदा कारत: सर, ये साइंटिफिक थ्योरीज दे रहे हैं। ...(**व्यवधान**)

श्री सभापति: एक मिनट बैठ जाइए। यह क्वेश्चन इंपोर्टेंट है। मैं समझता हूं कि इसको सेप्रेटली डिस्कस करना चाहिए। ...(व्यवधान)

DR. ANBUMANI RAMDOSS: Sir, let me answer this question. There is something called benefit risk ratio. You take the entity of what is the benefit, what is the risk, then, you take the ratio of that drug. That is what the experts, not only in India, but all around the world, they go according to the risk benefit ratio and we have DTAB, we have Pharmaco Vigilance Committee and we have experts on that.

Now, coming to the issue of Nimesulide, it was, in fact, in 2002, that the use of Nimesulide was suspended in Finland and Spain. Then, the European Agency for Evaluation of Medicinal Products, that is, EMEAH, initiated an extensive evaluation of Nimesulide drug. In fact, they say that it could be used again....(*Interruptions*)...

SHRIMATI BRINDA KARAT: I am sorry, Sir, he is misleading the House...(*Interruptions*)....

MR. CHAIRMAN: Let him finish.

DR. ANBUMANI RAMDOSS: Let me finish the answer.

MR. CHAIRMAN: Let him finish.

DR. ANBUMANI RAMDOSS: Let me finish the answer. What is the point in ...(*Interruptions*)...

SHRIMATI BRINDA KARAT: It is banned in the whole of Europe.

DR. ANBUMANI RAMDOSS: Sir, today, Nimesulide is being used in 50 countries around the world, including Italy, Spain...(*Interruptions*)...

SHRIMATI BRINDA KARAT: No, this is wrong, Sir. Italy has banned this drug...(*Interruptions*)...

MR. CHAIRMAN: Let him finish...(*Interruptions*)...Please take your seat...(*Interruptions*)...

DR. ANBUMANI RAMDOSS: Let me finish my answer. Let me finish my answer. ...(*Interruptions*)... Sir, she is a very good friend of mine and we interact quite closely on all these issues. ...(*Interruptions*)...

SHRIMATI BRINDA KARAT: There is no question of friendship as far as this is concerned. ...(*Interruptions*)...

DR. ANBUMANI RAMDOSS: I am trying to explain ...(*Interruptions*)...

SHRIMATI BRINDA KARAT: It has nothing to do with friendship....(*Interruptions*)...

DR. ANBUMANI RAMDOSS: Sir, I am trying to explain what we are trying to do. ...(*Interruptions*).. And, a PIL was also filed in the court here, in a Delhi court. In fact, we have gone through extensively about the issue. A lot of experts all around the country had taken part in the DTAB, the highest body which bans or approves a drug. In fact, the experts say that this could be used, and so literally fifty countries around the world have been using it. ...(*Interruptions*)...

SHRIMATI BRINDA KARAT: Give me the names of those countries. ...(*Interruptions*)...

DR. ANBUMANI RAMDOSS: But, Sir, this drug has been put under 'drugs of current interest'. We have formed a new Committee called the 'National pharmaco-Vigilahce Committee'. This Committee is going into the adverse drug reactions in respect of all the drugs, not only the new drugs but even in the case of the existing drugs also, and we have issued a notification...(*Interruptions*)...

SHRIMATI BRINDA KARAT: Sir, he is misleading the House.

DR. ANBUMANI RAMDOSS: Sir, we have issued a notification called 'Drugs of Current Interest', where this will be taken care of.

SHRIMATI BRINDA KARAT: Sir, he is not answering my question.

DR. ANBUMANI RAMDOSS: But, Sir, as far as the issue of 'Nimesulide' is concerned,—in fact, I was discussing it yesterday this with my officials—I would like to say that we will consider it. We will look more closely into that, and, if required, we may even take up the issue of de-listing it from the country. We may look at this. ...(*Interruptions*)...

SHRI DIPANKAR MUKHERJEE: What are you looking at?

DR. ANBUMANI RAMDOSS: After my officials give me a concrete evidence of ...(*Interruptions*)...

SHRIMATI BRINDA KARAT: Sir, what is this? ...(*Interruptions*)...

SHRI DIPANKAR MUKHERJEE: You are looking at it for years. We want a specific answer. What is the assurance? The Minister has to give

us a specific answer as to whether he is going to ban this drug or not. ...(*Interruptions*)...

श्री सभापति: बैठिए, बैठिये। ...(व्यवधान)... एक मिनट, एक मिनट सुन लीजिए। ...(व्यवधान)... एक मिनट सुन लीजिए। आप एक मिनट बैठ जाइये। ....(व्यवधान)... आप एक मिनट बैठिये तो सही। ....(व्यवधान).. मैं चाहता हूं कि ....(व्यवधान)...

SHRI DIPANKAR MUKHERJEE: Let him enlighten me. .....(*Interruptions*)... Please enlighten me. ....(*Interruptions*)... Let me enlighten what you want to do.

श्री सभापति: माननीय सदस्य, मैं चाहता हूं कि ...(व्यवधान)...

DR. ANBUMANI RAMDOSS: You are not competent, I am not competent to ban a drug. The authorities are competent, the experts are competent, the specialists are competent to ban it. You are not competent; I am not competent. I am not at all competent to ban any drug. ...(*Interruptions*)... I will be the last person to have any interest of these multinationals, and you know how I am fighting for the interest of these Indian manufacturers.

श्री सभापति: देखिये, माननीय सदस्य बैठ जाइये। ...(व्यवधान)... एक मिनट बैठिये। ...(व्यवधान)... माननीय सदस्य बैठ जाइये। ...(व्यवधान)... एक बार बैठ जाइये। प्लीज टेक योर सीट। ...(व्यवधान)... माननीय सदस्य, मैं इतना ही कहना चाहता हूं कि यह प्रश्न गंभीर है और इसके ऊपर चर्चा होनी चाहिए। आप अगर चाहें, तो इस पर half-an-hour discussion हो सकता है। ...(व्यवधान)... नेक्स्ट क्वेश्चन। ...(व्यवधान)...

SHRIMATI BRINDA KARAT: Sir, let him give an assurance on Nimesulide.

श्री नीलोत्पल बसु: सर, मेरा अनुरोध है कि एक समयबद्ध तरीके से फैसला लेकर मंत्री जी हाउस में आकर इसके बारे में बता दें। ...(व्यवधान)...

श्री सभापति: ठीक है जो आपने कहा है ...(व्यवधान)...

श्री नीलोत्पल बसु: आप तीन हफ्ते का टाइम इनको दे दीजिए। ...(व्यवधान)...

DR. ANBUMANI RAMDOSS: Sir, I am not in a position to decide. My officials have to decide. I have given a commitment that my officials will look into this issue, and if...(*Interruptions*)...

SHRI NILOTPAL BASU: Sir, it is a question of life and death of children. ...(*Interruptions*)...

MR. CHAIRMAN: Next question.

श्री अमर सिंह: सर, मामला गंभीर है। ...(व्यवधान)...

श्री ललित किशोर चतुर्वेदी: सभापति महोदय, यह बहुत महत्वपूर्ण प्रश्न है। ...(व्यवधान)...

श्री सभापति: आप छोड़िये। इस पर half-an-hour discussion होगा। We can have Half-an-Hour discussion on it. Next Question.

Suicides by farmers

*4. SHRI JANARDHANA POOJARY: Will the Minister of AGRICULTURE be pleased to state:

(a) whether it is a fact that suicides by farmers reeling under debt is on the increase across the country despite various relief packages announced by the State Governments and the Central Government; and

(b) if so, the details in this regard, including the relief packages announced, during the last three years, State-wise and year-wise?

THE MINISTER OF AGRICULTURE (SHRI SHARAD PAWAR): (a) and (b) A statement is laid on the Table of the House.

Statement

(a) and (b) The National Agricultural Insurance Scheme (Rashtriya Krishi Bima Yojana) is being implemented in the country from Rabi 1999-2000 season.

To provide relief in the event of natural calamities two schemes are under implementation by the Ministry of Home Affairs in terms of recommendations of the Finance Commission, *viz.* Calamity Relief Fund and the National Calamity Contingency Fund. Besides, the Ministry of Rural Development provides foodgrains free of cost under the special component of the Sampoorna Grameen Rozgar Yojana for generating relief employment for victims of natural calamities who suffer loss of employment.

SHRI JANARDHANA POOJARY: Sir, a large number of cases of suicide by farmers from several parts of the country, particularly, from Andhra Pradesh, Rajasthan, Karnataka, Maharashtra, Tripura have been reported. The problem of suicide by farmers has become a challenge for